



SPM Medicare Pvt. Ltd.

CIN: U33110DL2014PTC269667

Regd. Office: 414/5, Osian Building, 12 Nehru Place, New Delhi-110019
Factory address: B-40, Phase-II, Noida, Gautam Budh Nagar, U.P.-201305
Tel.: 0120-4270212 E-mail: info@spmmedicare.com
Website: www.spmmedicare.com

EC- DECLARATION OF CONFORMITY

1. **Organization Detail** : SPM MEDICARE PVT. LTD
B-40, Phase II, Noida, Gautam Buddh Nagar, UP- 201305, India.
Role : Manufacturer
SRN : IN-MF-000011829
2. We, M/s. SPM Medicare Pvt. Ltd., B-40, Phase II, Gautam Buddh Nagar, Noida-201305 (U.P) (INDIA) do hereby declare that we are solely responsible for the product manufactured and supplied by us and same complies with the essential requirements of the Medical Device Directive 93/42/EEC as amended by 2007/47/EC and as per additional requirement of legacy devices article 120 (3) of MDR 2017/745.
3. The company and its authorized representative shall fulfil the obligations imposed by CDSCO (India) and notified body and ensures and declares that the company's products shall meet all provisions of the ISO standards as applicable.
4. **Product Information:**
 - (a) **Product** : Sterile IV cannula for single use
 - (b) **Product Variants** : SPM/With/without injection port; with/without wings & with/without safety (14G,16G,17G, 18G, 20G, 22G, 24G & 26G)
 - (c) **Intended purpose** : The IV Cannula is a passive device to provide for the infusion of fluids, drugs, and/or blood components, or to facilitate the placement of Vascular Access devices.
5. **Risk Class** : IIa
6. **Harmonized Standard:** EN ISO 11135-1: 2014, EN ISO 11737-2:2019, EN ISO 14937 :2009, ISO 11607 1:2019, EN ISO 11607-2: 2019, EN ISO 15223-1:2016, EN ISO 10993 -7: 2016, EN ISO 9626 :2016 EN ISO 10555-1:2013, EN ISO 10555-5:2013 & EN ISO 80369-7:2021
7. The company undertakes to manufacture the product as per National/International Standards as specified in its quality system. The company has selected TUV Rheinland LGA Products GmbH, Tillystraße 2, 90431, Nürnberg, Notified Body No.: 0197 as Notified Body and authorizes the Notified Body to carry out necessary inspection and agrees to supply the required information and data / documents from time to time.
8. The company agrees to make available all document & data to the national authority for a period of Product Shelf Life + 2 Years.
9. The company and its authorized representative shall fulfill the obligations imposed by MDD and ensures and declares that the company's products shall meet all provisions of the directive as applicable.



BALMUNG

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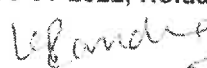
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10. The company undertakes to keep up to date a systematic procedure to review experience gained during post production phase and to implement appropriate means to apply and take necessary corrective action on account of the nature & risk in relation to the product.
11. The company undertakes to notify immediately any malfunction / deterioration of the performance of the device to the appropriate authority and shall recall such devices already placed in the market.

12. Notified body : TUV Rheinland LGA Products GmbH, Tillystraße 2, 90431, Nürnberg, (Notified Body No.: 0197)
Conformity assessment route: Annex V; Production Quality Assurance
EC certificate No : DD 1040862-1
Valid until : 26-05-2024

Date: 06-01-2022, Noida (India)


Authorized Signatory
Vivek Shankar Pandey
Director



SPM MEDICARE PVT. LTD
B-40, Phase II, Noida, Gautam Budh
Nagar, UP- 201305, India.
Web : www.spmmedicare.com

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EC REP

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